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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,136	07/03/2003	Mark W. Kroll	A03P1049	7187
36802	7590	03/02/2006	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			BERTRAM, ERIC D	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/613,136	Applicant(s) KROLL ET AL.	
	Examiner Eric D. Bertram	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/3/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 7/03/2003 was filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

2. The disclosure is objected to because of the following informalities: on page 4, line 26 it believed that "with the senor" should be -- with the sensor --. Please review the specification for further errors that may have been overlooked by the Examiner.

Appropriate correction is required.

Double Patenting

3. Claim 4 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 3. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, determining a final location from an initial location, as stated in claim 3, is substantially the same as determining a distance traveled, as stated in claim 4, especially since both values are calculated by the same procedure of double integration.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 5, 6, 9 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 5 and 9 recite the limitation "within the determined period" in line 3 of claim 5 and in line 2 of claim 9. There is insufficient antecedent basis for this limitation in the claims. Claim 1, on which claims 5 and 9 depend refers to a "determined interval," and it is unclear as to whether "the determined period" of claims 5 and 9 is the same time segment or a different segment of time.

7. Furthermore, claim 5 is indefinite since it recites the limitation "the device continuously evaluates the equivalent quantified activity during all time periods of the determined period within the total episode." It is unclear as to whether the device will evaluate activity only within the determined period, or if it will evaluate activity throughout the total episode, especially since a "time period" is never defined.

8. Claim 6 depends from claim 5, and as such is indefinite by its association.

9. Claim 28 recites the limitation "the given period" in line 1 of claim 28. There is insufficient antecedent basis for this limitation in the claims. Claims 15, 24 and 26, on which claim 28 depends, all discuss a "determined interval" and it is unclear if "the given period" of claim 28 is the same time segment or a different segment of time.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 2, 5, 6, 10, 14-18, 25-29 and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Stone et al (US 6,280,409). As shown in figure 7, Stone et al. disclose an implantable device 71a which utilizes an accelerometer 76a as an indicator of patient activity (Col. 9, lines 3-6). The accelerometer, which inherently measures acceleration (a measure of an object's position in space with respect to time), is in communication with the processor 77a, which evaluates the information from the accelerometer (Col. 7, lines 23-25), automatically determines when the accelerometer information is in excess of a threshold value (Col. 9, lines 6-9). The processor also determines a maximum equivalent quantified activity, or equivalent exertion index, during a determined interval. As described by Stone et al., the sensor records 2-second counts, of which consecutive counts can be grouped together to form 80-second determined intervals (Col. 9, lines 32-40). If an interval group exceeds a threshold, then it is considered the equivalent of true activity (Col. 9, lines 40-43). The number of non-overlapping groups over a 24 hour period which are considered true activity, e.g. walking (Col. 2, lines 35-45), are added to create a quantity signifying the total, or maximum amount, of activity completed in a day (Col. 9, lines 43-46). All the interval groups, including the group with the highest value, are stored in a memory 75a, which is

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in communication with the accelerometer. Stone et al. also disclose a telemetry circuit 83 in communication with the memory to send data related to patient activity to an external device such as programmer P, which displays the data, as shown in figure 7 (Col. 7, lines 28-37). Finally, figure 7 shows stimulation points 81 and 82, which could provide treatment to the heart upon detection of an arrhythmia (Col. 7, lines 45-50).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. ('409) in view of McClure et al. (US 5,549,652). Stone et al., as described above, disclose the applicant's basic invention with the exception of the device double integrating an acceleration signal in order to determine a distance traveled (i.e. distance from an initial location to a final location, or displacement) prior to determining the maximum equivalent quantified activity. Attention is directed to the reference of McClure et al., which discloses an accelerometer used to sense accelerations of cardiac tissue, wherein the accelerations are double integrated to determine cardiac displacement (Col. 7, lines 55-60). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the device of Stone et al. by double integrating sensed accelerations, as it is old and well known in the art that double integration will produce a displacement value.

16. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. ('409) in view of Mault (2002/0138213). Stone et al. disclose the applicant's basic invention with the exception of including a GPS sensor as a physical activity sensor that can determine a distance traveled. Attention is directed to the secondary reference of Mault, that discloses a physical activity sensor, such as a GPS, which helps determine the distance traveled based on repetition rate and speed (paragraph 0042). Therefore, it would have obvious to one of ordinary skill in the art at the time of

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the applicant's invention to include a GPS sensor as a physical activity sensor since this is old and well known in the art.

17. Claims 11, 12, 19, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. ('409) in view of Stropkay (US 4,659,077). Stone et al., as described above, disclose the applicant's basic invention with the exception of determining an equivalent distance traveled, specifically by updating velocity values. Attention is directed to the secondary reference of Stropkay, that discloses an exercise device that determines the equivalent distance traveled by a user. Stropkay describes a system that can calculate total distance traveled over the interval of an exercise session (Col. 6, 45-50). Furthermore, the device would inherently determine the total distance traveled by periodically incrementing the initial distance with calculated equivalent distance data. That is to say that in order to display total distance traveled by a user to date, the distance would need to be continuously summed. While this device does not refer to implantable devices, it accomplishes the same function as claimed by the applicant, that being of converting patient movement into a distance traveled. Therefore it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the device of Stone et al. to calculate distance traveled, as this is a known technique in the art of activity sensors.

18. Claims 13 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. ('409). Stone et al., as described above, disclose the applicant's basic inventive entity except for the determined interval specifically being 6 minutes. However, since the determined intervals merely consist of a grouping of 2-second

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counts, it would be possible to combine 120 consecutive groups to comprise a 6 minute interval. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to change the interval time of Stone et al. to 6 minutes, because Stone et al. discloses that a 6 minute walk test is a common clinical tool used to assess patient activity (Col. 2, lines 58-63).

19. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. ('409) in view of Stropkay ('077) and further in view of McClure et al. ('652). Stone et al., as modified above, disclose the applicant's basic invention with the exception of double integrating an acceleration signal in order to increment distance traveled.

Attention is directed to the reference of McClure et al., that discloses double integrating an acceleration signal from the body in order to determine displacement. It would be obvious to continuously add these signals to determine total displacement. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the device of Stone et al. by double integrating an acceleration to determine distance traveled since this was a known method in the art.

20. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. ('409) in view of Stropkay ('077) and further in view of Mault ('213). Stone et al., as modified above, disclose the applicant's basic invention with the exception of the use of a position sensor and the use of velocity values. Attention is directed to the reference of Mault, that discloses the use of a GPS position sensor, which allows for the determination of speed, or velocity, values. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's

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invention to modify the system of Stone et al. by using a position sensor and velocity values to help to determine distance traveled since these techniques are old in the art of activity monitoring.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kroll et al. (US 6,625,493) and Prutchi et al. (US 5,978,713) disclose an implantable, accelerometer-based activity sensor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday and every other Friday from 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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